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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/438,872	11/12/1999	KENT C. COCHRUM	44041.010400	9965

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EXAMINER
MARX, IRENE

ART UNIT	PAPER NUMBER
1651	21

DATE MAILED: 07/24/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/438,872	Applicant(s) Cochrum et al.
	Examiner Irene Marx	Art Unit 1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *May 16, 2002* .

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1, 3, 9, 11-13, and 29-36* is/are pending in the application.

4a) Of the above, claim(s) *29-36* is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1, 3, 9, and 11-13* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☒ Interview Summary (PTO-413) Paper No(s). 20
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

The application should be reviewed for errors. Error occurs, for example, in the spelling of "antiviral" in claim 13.

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/18/02 has been entered.

The amendment filed 7/9/02 is acknowledged. Claims 1, 3, 9, and 11-13 are being considered on the merits. Claims 14-24, 26, 28 and 37, 40-42 and 45-63 are cancelled. Non-elected claims 29-36 are withdrawn from consideration.

Claim Rejections - 35 USC § 112

INDEFINITE

Claims 1, 3, 9, and 11-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague and indefinite in that it cannot be readily assessed what is intended to be encompassed by "other ancillary substances" with respect to "clotting factors", "which initiate the physiological clotting process when applied to the bleeding site" since the identity and nature of these "substances" is not clearly delineated in the as-filed specification.

Claim 3 is confusing in reciting that the dressing further comprises a substrate. It is unclear what a substrate is and how the substrate is related to the zone, the matrix and/or the hemostatic agent in this context. A claim to a composition should describe how the part of the composition are related to one another. It is unclear if by "substrate" applicants intend the patient, for example.

Claim 13 is confusing in the recitation of "at least one of" followed by "and mixtures thereof". The claim is also confusing in the recitation of "or" within the listing of elements, followed by "and". It is unclear what is included or excluded.

Claim Rejections - 35 USC § 102

Claims 1, 3, 9, 12 and 13 remain rejected under 35 U.S.C. 102(b) as being clearly anticipated by G.B. 1454055 [N].

G.B. 1454055 discloses a wound dressing comprising dextran-epichlorohydrin polymer particles or beads and a matrix which may be paper, cotton fabric, inert plastics, etc. (page 6). Disinfectants may be added to the carrier (page 6, l. 36). Sterilization may be by gamma irradiation (p. 6, l. 130).

With respect to the added limitation regarding the property of the cross-linked dextran of triggering release of "clotting factors and other ancillary substances", this function is an inherent property of cross-linked dextrans.

Claim Rejections - 35 USC § 103

Claim 11 remains rejected under 35 U.S.C. 103(a) as being unpatentable over G.B. 1454055 [N] as applied to claims 1, 3, 9, 12 and 13 above, and further in view of Larson [R] or Eloy *et al.* [S] and Wang (US 5196190 [B]).

The claim is directed to a dry, stable, sterile wound dressing comprising a matrix containing a hemostatic polymer such as cross-linked dextran and collagen or thrombin or fibrinogen.

Collagen, fibrinogen or thrombin are known hemostatic agents as describe by Larson [R] or Eloy *et al.* [S]

Wang teaches that cross-linked dextran has hemostatic properties (col. 10, l. 50).

The addition of thrombin or fibrinogen or collagen to the wound dressing of G.B. 1454055 would have been obvious when the reference was taken with Larson or Eloy *et al.* and Wang because cross-linked dextran, thrombin, fibrinogen and collagen are known hemostatic agents and have been used in the past as such.

It is well known that it is prima facie obvious to combine two or more ingredients each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is useful for the same purpose. The idea for combining them flows logically from their having been used individually in the prior art. In re Pinten, 459 F.2d 1053, 173 USPQ

801 (CCPA 1972); In re Susi, 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169 USPQ 423, 426 (1971); In re Crockett, 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960).

Thus, the claimed invention as a whole was clearly prima facie obvious, especially in the absence of evidence to the contrary.

Response to Arguments

Applicants argue that the material intended by the '055 patent wishes to avoid rapid blood coagulation. However, it is apparent from the reference that while one of the embodiments wishes to exclude the formation of a fibrin and fibrin coagulum because of the influence of thrombin (page 3, lines 95-105), other embodiments do not exclude the triggering of release of clotting factors and other ancillary substances which initiate a physiological clotting process when applied to the bleeding site. It is noted that the claimed designated composition is not limited to a particular crosslinked dextran. On the contrary, the composition claims under examination do not have any size exclusion requirements for the cross-linked dextran beads, but merely recite a desired result. Applicants argue that their desired result would not flow from the use of the prior art dressing because the prior art bead excludes fibrinogen, while their bead concentrates fibrinogen on the surface of the bead. This appears to be essentially the same function as in the prior art disclosure. On page 20 of the instant specification, it is explained that fibrinogen is excluded from the interior of the bead (just outside the first layer) and that fibrinogen has a MW of about 340,000 Da. As the prior art bead has an exclusion range of 270,000 to 50,000 Da, fibrinogen would be excluded from the interior of the prior art bead in a similar fashion. As the prior art bead is composed of the same material as the instant bead, has about the same exclusion properties and size, it is reasonably assumed to function in the same manner.

In spite of applicant's arguments to substantiate the claimed article as novel or unobvious, insofar as the limitations of the article rely on elements that instead of being characterized by specific technical features suitable for the identification of an article, are imprecisely defined by

means of functional features which merely recite the desired result to be achieved, the subject matter is still considered to be anticipated or obvious over the disclosures of the prior art.

It is emphasized that the claims under examination are composition claims, not method claims and arguments directed to the intended use of a composition or limitations directed to the intended use of a composition, are of little patentable weight.

With respect to the added limitation of triggering release of "clotting factors and other ancillary substances", this function is an intrinsic function of a hemostatic agent composition comprising beads of cross-linked dextrans, as indicated *supra,* and applicants have not shown otherwise with objective evidence.

Therefore the rejections are deemed proper and are adhered to.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (703) 308-2922. The examiner can normally be reached on Monday through Friday from 6:30 AM to 3:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743. The appropriate fax phone number for the organization where this application or proceeding is assigned is before final (703) 872-9306 and after final, (703) 872-9307.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Customer Service whose telephone number is (703) 308-0198 or the receptionist whose telephone number is (703) 308-1235.

Irene Marx
Primary Examiner
Art Unit 1651